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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,750	02/02/2001	Berend Jongsma	AHP-98248 P1	9381

7590 06/18/2003

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,750	JONGSMA ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,18,19,21,22,24 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,18,19, 21,22,24 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

In paper no. 19, applicant cancelled claims 25, 26, 27, amended claims 15, 16, 19, 24, 28, 29 and added new claims 30-32. Claims 15, 16, 18, 19, 21, 22, 24 and 28-32 are under consideration.

Request for Continued Examination

The request filed on 3/25/03 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/775750 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 16, 18, 24 and 28-31 rejected under 35 U.S.C. 102(b) as being anticipated by Wakenell et al. (American Journal of Veterinary Research. 1986; 47 (4): 933-938).

Claims 15 and 24 are drawn to an in ovo vaccine and a method of vaccinating chickens having maternal antibodies to infectious bronchitis virus by administering a vaccine comprising a live, avirulent strain of infectious bronchitis (IB) virus. The immunologically effective amount of the vaccine administered in claims 15, 24, 28 and 29 ranges between 10^{-1} EID_{50} to $10^{2.0}$ EID_{50} per egg. Claims 30 and 31 state that the vaccine is reconstituted prior to administration and that the vaccine has not been approved for in ovo administration. Claim 18 states that the vaccine comprises substantially no virus neutralizing factor. The vaccine protects at least 89% of 3-

week-old post-hatch chicks against challenge from virulent IB virus. Claim 16 requires that at least 72% of the in ovo vaccinated chickens hatch.

Wakenell et al. anticipate an in ovo vaccine comprising a live, avirulent infectious bronchitis virus, P_{20}-IBV. Wakenell et al. also teach a method of vaccinating maternal antibody positive chicken embryos by administering P_{20}-IBV, see the first line of Table 4 on page 936. The vaccine of Wakenell et al. is reconstituted before administration, see the paragraph bridging pages 933-934 and the next paragraph. Wakenell et al. teach that the commercially available viral vaccine, Massachusetts 41, is pathogenic in embryos, see the introduction section. This strain is rendered avirulent in the materials and methods section. Wakenell et al. anticipate 81% of the vaccinated chicks hatch in line 1 of Table 4 on page 936 upon administration of P_{20}-IBV. Wakenell et al. also anticipate protecting 100% of 4-week-old chicks against signs of respiratory tract disease and against isolation of C-IBV upon challenge with virulent Massachusetts strain 41, C-IBV, see the first line of Table 4.

Wakenell et al. teach different unit dosages of administering the virus from the dosage units recited in the claims. However, since the vaccine of Wakenell et al. anticipate the vaccine administered, the required percentage of chicks that hatch and the percentage of chicks protected against disease, it is determined that the dose administered by Wakenell et al. and the dose recited in the instant claims are equivalent because the outcome is the same. Therefore, Wakenell et al. anticipate claims 15, 16, 18, 24 and 28-31.

Applicant has submitted a declaration by Frans Davelaar under 37 CFR § 1.132. Applicant argues that the efficacy of the instant virus is at least 89% while the efficacy against

challenge from IB viral challenge in the data generated by Wakenell et al. ranges between 50% to 86% in Tables 4 and 5.

Applicant's arguments presented in the response and the declaration have been considered, but are found unpersuasive. The data of Wakenell et al. referred to by applicant is observed when the embryos are administered avirulent virus, P_{40}-IBV. Wakenell et al. clearly anticipate the % efficacy and the % hatchability recited in the claims with live, avirulent IB virus, P_{20}-IBV, administered to maternal antibody positive chicken embryos. Wakenell et al. state that a direct comparison between P_{20}-IBV and P_{40}-IBV "was not possible because of different dosage levels and challenge exposure times used", see the first column on page 937. Therefore, the ineffectiveness of P_{40}-IBV in maternal antibody positive chicks is irrelevant to the anticipatory data observed for P_{20}-IBV.

Applicant admits that the methodology used to determine efficacy in the instant application and Wakenell et al. are "clearly comparable". Applicant also provides a reference supporting this assertion. Therefore, it is clear that the results obtained by the methodologies of Wakenell et al. are comparable to the results obtained in the instant application. Wakenell et al. anticipate the results claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 21, 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakenell et al. supra.

Claims 19 and 32 state that the vaccine is Massachusetts serotype 1263. Claims 19, 21 and 22 state that the vaccine is administered in a dose range between 10^{-1} EID_{50} to $10^{2.0}$ EID_{50} per egg.

See the teachings of Wakenell et al. above. The reference does not teach administering Massachusetts serotype 1263.

However, the reference teaches embryonic protection administering a commercially available IBV vaccine that is not approved for in ovo administration, see the introduction and "Viruses" section bridging pages 933-934. The specification admits that Massachusetts serotype 1263 is commercially available in lines 11-12 on page 5. Therefore, using another commercially available IBV vaccine would be an obvious alternative to the Massachusetts type used by Wakenell et al. with a reasonable expectation of success. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
June 6, 2003

JAMES HOUSEL 6/16/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600